



**APPENDIX A: CLAIMS PENDING PRIOR TO**  
**RESPONSE TO OFFICE ACTION DATED JULY 25, 2006 FOR 09/776,250**

13.-20. CANCELED

21. (Original) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient:

(a) on the first day of treatment, a composition comprising autologous tumor cells or tumor cell extracts which corresponds to from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells free of any adjuvant;

(b) four to seven day after initiation of the treatment an immunomodulatory agent that potentiates protective anti-tumor immunity or inhibits immune suppression or both; and

(c) at least one additional composition comprising autologous tumor cells or tumor cell extracts.

22. (Original) The method of claim 21, in which the immunomodulatory compound is cyclophosphamide.

23. (Original) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient:

(a) on the first day of treatment, a composition comprising a haptenized autologous tumor cell or tumor cell extract which corresponds to from about  $2 \times 10^5$  to  $2.5 \times 10^6$  tumor cells free from any adjuvant;

(b) four to seven days after initiation of the treatment, cyclophosphamide; and

(c) at least one week after initiation of the treatment, a composition comprising an adjuvant and a haptenized autologous tumor cell or tumor cell extract which corresponds to from about  $2 \times 10^5$  to about  $1 \times 10^7$  tumor cells.

24. (Amended) The method in claim 23, in which the adjuvant is *Bacille Calmette-Guerin*.

25. (New) The method of claim 21, wherein the tumor cells or tumor cell extract is haptenized.

26. (New) The method of claim 21, wherein the tumor cells or tumor cell extract is a mixture of haptenized and non-haptenized tumor cells or tumor cell extract.

27. (New) The method of claim 21, wherein at least one of the tumor cell or tumor cell extract composition is haptenized.

28. (New) The method of claim 26, where the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.

29. (New) The method of claim 28, in which the hapten is dinitrophenyl.

30. (New) The method of claim 21, wherein the tumor cell extract comprises tumor cell membrane components.

31. (New) The method of claim 21, wherein the tumor cell extract comprises tumor cell polypeptides.

32. (New) The method of claim 21, wherein the tumor cells or tumor cell extracts originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.
33. (New) The method of claim 21, wherein the tumor is melanoma.
34. (New) The method of claim 21, wherein the tumor is ovarian cancer.
35. (New) The method of claim 21, wherein the tumor cell or tumor cell equivalents are rendered incapable of growth or multiplication *in vivo*.
36. (New) The method of claim 31, wherein the tumor cell or tumor cell equivalents are rendered incapable of growth or multiplication *in vivo* by irradiation.
37. (New) The method of claim 31, wherein the tumor cells or tumor cell equivalents are rendered incapable of growth or multiplication *in vivo* by haptenization.
38. (New) The method of claim 21, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.
39. (New) The method of claim 21, wherein the mammalian patient is a domestic pet or livestock.
40. (New) The method of claim 21, wherein the immunomodulatory agent is administered 5 to 7 days after initiation of the treatment.
41. (New) The method of claim 21, wherein the patient is a human.
42. (New) The method of claim 23 wherein the mammalian patient is a domestic pet or livestock.
43. (New) The method of claim 23, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin
44. (New) The method of claim 23, wherein the patient is a human.

45. (New) The method of claim 23, wherein the immunomodulatory agent is administered 5 to 7 days after initiation of the treatment.

46. (New) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient a composition comprising a haptenized or a non-haptenized tumor cell comprising from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells or tumor cell equivalents per dose, without any adjuvant, wherein the tumor cells or cell equivalents are conjugated to a hapten, and rendered incapable of growth or multiplication in vivo, prior to a second composition comprising an adjuvant and a tumor cell, which second composition contains from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cell or tumor cell equivalents, wherein the tumor cell or tumor cell equivalents are conjugated to a hapten.

47. (New) The method of claim 46, wherein the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.

48. (New) The method of claim 46, wherein the tumor is melanoma.

49. (New) The method of claim 46, wherein the tumor is ovarian cancer.

50. (New) The method of claim 46, wherein the adjuvant is selected from the group consisting of *Bacille-Calmette-Guerin*, Q-21, and detoxified endotoxin.

51. (New) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient:

(a) on the first day of the treatment, a composition comprising autologous tumor cells, which corresponds to from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells, free of any adjuvant;

(b) four to seven days after initiation of the treatment, an immunomodulatory agent that potentiates protective anti-tumor immunity or inhibits immune suppression, or both; and

(c) at least one additional composition comprising autologous tumor cells.

52. (New) The method of claim 51, wherein the tumor is melanoma.

53. (New) The method of claim 51, wherein the tumor is ovarian cancer.

54. (New) The method of claim 51, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

55. (New) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which, method comprises administering to the patient:

(a) on the first day of treatment, a composition comprising a haptenized autologous tumor cell which corresponds to from about  $2 \times 10^5$  to  $2.5 \times 10^6$  tumor cells free from any adjuvant;

(b) four to seven days after initiation of the treatment, cyclophosphamide; and

(c) at least one week after initiation of the treatment, a composition comprising an adjuvant and a haptenized autologous tumor cell which corresponds to from  $2 \times 10^5$  to  $1 \times 10^7$  tumor cells.

56. (New) The method of claim 55, in which the adjuvant is *Bacille Calmette-Guerin*.